Remarks

Claims 1-18 and 24-28 are pending in this application, and subject to a Restriction Requirement. No amendments are made to the claims or specification.

Telephone Interview

Applicants thank Examiner Seharaseyon for the telephone interview on August 1, 2006, during which the restriction requirement was discussed in the context of prosecution in the parent application (US 09/744,754, now issued as US 6,685,933). Specific aspects of the telephone interview are explored more fully below. Though agreement was not reached on all issues, Applicants believe that this response is in accord with suggestions made by the Examiner.

Restriction Requirement

It is alleged that the pending claims define two inventions: An interferon alpha hybrid protein (claims 1-14, 18, and 28; Group I), and a nucleic acid, vectors and cells (claims 15-17, and 24-27; Group II). Applicants traverse the requirement for election between these two Groups, at least because claims of similar scope were examined together in the parent application.

Applicants thank the Examiner for indicating during the interview that the claims of Group II would be recombined with the claims of Group I, upon allowance of the Group II claims. In view of this, Applicants elect the claims of **Group I** for prosecution in the current case. If it is necessary, please also consider this an express request to recombine the claims of Group II during prosecution.

Sequence Election

The Restriction Requirement further indicates that the claims are drawn to multiple sequences (*e.g.*, SEQ ID NOs: 9, 11, 30, 32, 36, 38, 40, and 42 as noted in claim 10), each of which is alleged to be an "independent and distinct" invention "because no common structural or functional properties are shared." Applicants are required to elect a single sequence as a single invention to be considered in the current application. Applicants traverse this requirement, at

least because the claims define a genus of closely related interferon alpha hybrid proteins that share significant structural similarity, as argued below.

Applicants draw the Examiner's attention to the telephone interview that took place on May 12, 2003, during prosecution of the parent application, between the Examiner, Supervising Examiner Spector, and Applicants' undersigned representative. During that interview, the claim structure used in the current application (and the parent application) was proposed and discussed extensively – particularly with regard to the four-part definition of the sequence of a hybrid interferon-α polypeptide.

The current claims are directed to hybrid interferon alphas that can be generically referred to as "HY-1-like" hybrids. That is to say, they share significant structural characteristics with the HY-1 hybrid (SEQ ID NO: 9), which can be represented generally as "α21b – X – α2c". For easy reference, the following Table is provided (a version of which was first provided to the Examiner in preparation for the May 12, 2003, telephone interview in the parent application). The Table illustrates which amino acid residues (in specific fusions in the subject claims) correspond to which source interferon-α polypeptide; for instance, shaded boxes in the table correspond to sequences from interferon α21b. Sequence identifiers are provided for each fusion in bold, in the first column (*e.g.*, **ID: 9** corresponds to HY-1).

	Amino Acid Residue			
	1-75	**76-81**	**82-95**	**96-166**
α21b – X – α2c Structure:				
HY-1 **(ID: 9)**	α21b	α2c	α2c	α2c
HY-2 **(ID: 11)**	α21b	α21b	α21b	α2c
HY-4 **(ID: 30)**	α21b	α2c	α21b	α2c
HY-5 **(ID: 32)**	α21b	α21b	α2c	α2c
SDM-1 **(ID: 36)**	α21b	α2c	α21b – mutant 1	α2c
SDM-2 **(ID: 38)**	α21b	α2c	α21b – mutant 2	α2c
SDM-3 **(ID: 40)**	α21b	α21b	α2c – mutant 1	α2c
SDM-4 **(ID: 42)**	α21b	α21b	α2c – mutant 2	α2c

It is apparent from the Table that each of SEQ ID NOs: 9, 11, 30, 32, 36, 38, 40, and 42 ("HY-1-like" fusions) share all of amino acids 1-75 (from α21b) and 96-166 (from α2c) in common.

Even the middle part of the fusion proteins (defined in claim 1 as the "second" and "third" amino acid sequences) contains very little variation within the defined genus. These middle segments are either the specified residues of interferon-α2c or the specified residues of interferon-α21b (shaded boxes); provided that two residues in the third amino acid segment (corresponding to residues 86 and 90 of interferon-α2c or interferon-α21b) may be any amino acid residue. For the Examiner's convenience, "LDKFXTELXQQLND" (as recited in claim 1) is the sequence of interferon-α2c corresponding to residues 82-95 except for variable positions 86 and 90, and "LEKFXTELXQQLND" (as further recited in claim 1) is the sequence of interferon-α21b corresponding to residues 82-95 except for variable positions 86 and 90.

To assist the Examiner and illustrate the structural similarity shared by the HY-1-like hybrids, we have aligned HY-1 and HY-2 (similar to Figure 5 of the application) with HY-4, HY-5, SDM-1, SDM-2, SDM-3, and SDM-4, as shown below:

Residues 1-60

HY-1	CDLPQTHSLGNRRALILLAQMGRISPFSCLKDRHDFGFPQEEFDGNQFQKAQAISVLHEM
HY-2	CDLPQTHSLGNRRALILLAQMGRISPFSCLKDRHDFGFPQEEFDGNQFQKAQAISVLHEM
HY-4	CDLPQTHSLGNRRALILLAQMGRISPFSCLKDRHDFGFPQEEFDGNQFQKAQAISVLHEM
HY-5	CDLPQTHSLGNRRALILLAQMGRISPFSCLKDRHDFGFPQEEFDGNQFQKAQAISVLHEM
SDM-1	CDLPQTHSLGNRRALILLAQMGRISPFSCLKDRHDFGFPQEEFDGNQFQKAQAISVLHEM
SDM-2	CDLPQTHSLGNRRALILLAQMGRISPFSCLKDRHDFGFPQEEFDGNQFQKAQAISVLHEM
SDM-3	CDLPQTHSLGNRRALILLAQMGRISPFSCLKDRHDFGFPQEEFDGNQFQKAQAISVLHEM
SDM-4	CDLPQTHSLGNRRALILLAQMGRISPFSCLKDRHDFGFPQEEFDGNQFQKAQAISVLHEM

Residues 61-120

HY-1	IQQTFNLFSTKDSSAAWDETLLDKFYTELYQQLNDLEACVIQGVGVTETPLMKEDSILAV
HY-2	IQQTFNLFSTKDSSATWEQSLLEKFSTELNQQLNDLEACVIQGVGVTETPLMKEDSILAV
HY-4	IQQTFNLFSTKDSSAAWDETLLEKFSTELNQQLNDLEACVIQGVGVTETPLMKEDSILAV
HY-5	IQQTFNLFSTKDSSATWEQSLLDKFYTELYQQLNDLEACVIQGVGVTETPLMKEDSILAV
SDM-1	IQQTFNLFSTKDSSAAWDETLLEKFYTELNQQLNDLEACVIQGVGVTETPLMKEDSILAV
SDM-2	IQQTFNLFSTKDSSAAWDETLLEKFSTELYQQLNDLEACVIQGVGVTETPLMKEDSILAV
SDM-3	IQQTFNLFSTKDSSATWEQSLLDKFSTELYQQLNDLEACVIQGVGVTETPLMKEDSILAV
SDM-4	IQQTFNLFSTKDSSATWEQSLLDKFYTELNQQLNDLEACVIQGVGVTETPLMKEDSILAV

Residues 121-166

HY-1	RKYFQRITLYLKEKKYSPCAWEVVRAEIMRSFSLSTNLQESLRSKE
HY-2	RKYFQRITLYLKEKKYSPCAWEVVRAEIMRSFSLSTNLQESLRSKE
HY-4	RKYFQRITLYLKEKKYSPCAWEVVRAEIMRSFSLSTNLQESLRSKE
HY-5	RKYFQRITLYLKEKKYSPCAWEVVRAEIMRSFSLSTNLQESLRSKE
SDM-1	RKYFQRITLYLKEKKYSPCAWEVVRAEIMRSFSLSTNLQESLRSKE
SDM-2	RKYFQRITLYLKEKKYSPCAWEVVRAEIMRSFSLSTNLQESLRSKE
SDM-3	RKYFQRITLYLKEKKYSPCAWEVVRAEIMRSFSLSTNLQESLRSKE
SDM-4	RKYFQRITLYLKEKKYSPCAWEVVRAEIMRSFSLSTNLQESLRSKE

The foregoing alignment of eight specific hybrid interferon-α polypeptides encompassed within the scope of the pending claims (and disclosed in the original specification and sequence listing) shows that **159 out of 166 amino acids are identical** within the narrowly defined and claimed genus. Non-identical amino acid residues are present only at positions 76, 78, 79, 80, 83, 86, and 90 (as indicated by shading in the above alignment). There is thus no undue burden on the Office to keeping the entire defined and claimed genus in the current case, since the sequences are all very similar, defined by common structural elements (*e.g.*, 159 out of 166 amino acids).

Further, it is noted that members of the genus of polypeptides share functional properties (since claim 1 requires that "the hybrid interferon-α polypeptide has interferon-α protein biological activity"). Thus, in contradiction to the statements made at page 3 of the current Office action, the claimed sequences (including the genus defined in claim 1, as well as the specific sequences defined by SEQ ID NOs: 9, 11, 30, 32, 36, 38, 40, and 42 as noted in claim 10) share common structural and functional properties, and should be maintained in this case.

Solely to satisfy the provisions of 37 C.F.R. 1.143, Applicants provisionally elect (under protest) SEQ ID NO: 36 (SDM-1), for initial prosecution. Based on the arguments above, Applicants request that this sequence be used for a preliminary search, and all the remaining sequences be rejoined and examined in the case once the first sequence (or the generic sequence defined in claim 1) is found to be free of the prior art.

Conclusion

Examiner Seharaseyon is invited to telephone the undersigned if any questions remain concerning the requirement for restriction, or the amendments made herein. Otherwise, the present application is ready for substantive examination, and such action is requested.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

By /Tanya M. Harding/
Tanya M. Harding, Ph.D.
Registration No. 42,630